K081313

510(k) SUMMARY

SUBMITTER:

Sorin Group Italia S.r.l.
86, Via Statale 12 Nord
41037 Mirandola (MO) Italy

NOV 19 2008

CONTACT PERSON:

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DATE PREPARED:

November 30, 2007

DEVICE TRADE NAME:

SH14 Hemoconcentrator

COMMON NAME:

Hemoconcentrator

CLASSIFICATION NAME:

Dialyzer, High Permeability With or Without Sealed Dialysate System

PREDICATE DEVICES:

Gambro HC 14R Hemoconcentrator (K951311) hereinafter referred to as HC1400 Maxi
Dideco DHF 0.6 Hemoconcentrator (K021732)

DEVICE DESCRIPTION:

The SH14 Hemoconcentrator is a hollow fiber type hemoconcentrator available for adult patients consisting of an external transparent housing with two filtrate ports on the cylindrical body and a fiber bundle. These fibers are bonded within the housing with polyurethane. A transparent blood header cap with a male Pos-Lock port is bonded to each end of the housing.

INDICATION FOR USE:

The SH14 hemoconcentrator is intended for use in cardiopulmonary bypass circuits for hemoconcentration and consequent restoring of patient's physiological hematocrit. The choice of hemoconcentrator depends on the protocol being used and required filtration rate. The device is intended to be used for six hours or less.

TECHNOLOGICAL CHARACTERISTICS:

The design, operating principles and control mechanisms are exactly the same for the SH14 Hemoconcentrator and Sorin Group USA HC1400 Maxi. They share similar intended use and the same design, patient population, performance characteristics, technological characteristics and manufacturing processes. The SH14 has exactly the same intended use, materials, manufacturing processes and biocompatibility of DHF 0.6 predicate. The basic function of all the above mentioned hemoconcentrators is the same. That is, the removal of excess fluid from patient's blood during or after cardiopulmonary bypass procedures resulting in hemoconcentration and restoring of patient's physiological hematocrit.

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Diluted blood is drawn, from the patient, inside the fibers of the device while plasma water is removed across the semi-permeable hollow fibers from the blood pathway to the filtrate side. The SH hemoconcentrator is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only.

BIOCOMPATIBILITY TEST RESULTS:

A complete battery of tests were carried out in accordance with the requirements of ISO 10993-1:1995 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing on the raw materials. Testing was performed on the SH14 (accelerated aging up to three years). The device was tested for Hemolysis, Hemocompatibility, Cytotoxicity, Irritation, Acute Systemic Toxicity and Mutagenicity. Sterility, Pyrogenicity, ETO residuals and package integrity testing were also conducted. The results of the testing met established specifications.

***IN VITRO* TEST RESULTS:**

In vitro testing were carried out in accordance with the requirements of "Guidance for the content of premarket notifications for conventional and high permeability hemodyalizers, August 7, 1998" where applicable for providing the data necessary to demonstrate both the substantial equivalence with the predicate device and also compliant with safety and effectiveness requirements. The device was aged and tested for: Mechanical integrity, Priming Volume, Pressure Drop, Ultrafiltration rate, Sieving coefficient, Hemolysis. The results of these tests met established specifications. For comparative purposes, the same testing, when applicable, has been conducted also on the aged Sorin Group USA HC1400 Maxi predicate device and non aged SH14. The shipping carton passed the basic testing and was still capable of providing adequate protection for further handling.

Data collected show that functional and biocompatibility parameters exhibited by the currently marketed Sorin Group USA HC1400 Maxi and DHF 0.6 apply to the SH14.

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the SH14 hemoconcentrator performs in a manner substantially equivalent to the predicate device. Biocompatibility studies demonstrate that the device is biocompatible according to its intended use. Additional testing has also demonstrated the effectiveness of production techniques to assure that the hemoconcentrator is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2008

Sorin Group Italia S.r.l.
c/o Barry Sall, RAC
Principal Consultant
PAREXEL Consulting
200 West Street
WALTHAM MA 02451

Re: K081313
Trade/Device Name: SH14 Hemoconcentrator
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: November 13, 2008
Received: November 13, 2008

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

Sorin Group Italia S.r.l.

510(k) Number (if known): K081313

Device Name: SH14 Hemoconcentrator

Indications For Use:

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Prescription Use __X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K081313